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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,872

Applicant(s)

WAI-CHIU SO ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Receipt of Request for Continued Examination and Amendments/Remarks received on August 19, 2004 is acknowledged. Claims **1-6 and 8-24** are pending in this application. Claim 7 and 25 stand cancelled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-9, and 12-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/124197.

Although the conflicting claims are not identical, they are not patentably distinct from each other since the subject matter claimed in both applications is similar.

Instant application is directed to a topical composition containing A) at least 5% of a piperidinopyrimidine, B) an acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof, C) a solvent selected from water and/or a lower alcohol, and D) a co-solvent

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selected from an aromatic or polyhydric alcohol in the amount of less than 10%, wherein the composition is in the form of a solution, tonic, ointment, mousse, a foam, shampoo, an aerosol, gel, paste, and cream.

Co-pending application is directed to a topical composition containing A) at least 5% of a piperidinopyrimidine, B) an acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof, C) a solvent selected from water and/or a lower alcohol, and D) a co-solvent a co-solvent of a polyhydric alcohol selected from 3-butylene glycol, polyethylene glycol, hexylene glycol, dipropylene glycol, glycerol or propylene glycol at less than approximately 10% by weight, wherein the final product is a foam or a mousse.

Thus, the instant subject matter is the generic scope in relation to the species claimed in co-pending application. Therefore, the co-pending claims are encompassed by instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-6, 8-9, 12-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) by itself or optionally in view of WO 97/12602.

Bazzano teaches a minoxidil composition to increase growth rate and stimulate new hair growth by administering a lotion containing 0.01-0.1% retinoic acid, 0.5-5% minoxidil, ethanol, 5-50% propylene glycol, 0.1% BHT, and distilled water (up to 10%). Formulation example II contains 1% retinoic acid, 10% minoxidil, 4% cetyl alcohol, 4% ethanol, and up to 100% water. Bazzano teaches the use of pharmaceutically acceptable acid salt. See column 19, lines 1-25. Bazzano states that minoxidil or its derivatives and analogs that are described in US patents 5910928, 3637697, 3461461, 4139619, and 4596812 are incorporated into the reference. US patent 3,461,461 teaches the acid salt derivatives including lactic acid and other instantly claimed acids of minoxidil. Bazzano discloses that a major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds cause excellent absorption of the hair follicles. See column 19, lines 35-40. The formulation can contain any pharmaceutically acceptable carrier, additive, or solubilizer.

Although Bazzano states that a minoxidil derivative/analog may be utilized, Bazzano does not explicitly teach the use of an acid addition.

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WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Bazaano and utilize instant minoxidil acid salt. One would be motivated to do so since Bazzano teaches the suitability of minoxidil or its derivative in the composition and Bazzano's teachings incorporate other US patents wherein the instant acid salt derivative is taught. Therefore, one could reasonably expect similar results with the use of a minoxidil acid salt derivative.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of WO and be further motivated to utilize the instant acid derivative. One would have been motivated to do so since both references teach that by adding salt to minoxidil, one obtains a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Further, since Bazzano is concerned with penetration of the composition into the hair follicle one would expect an additive effect of increasing penetration of the composition by adding instant salt. Lastly, WO demonstrates that it is known in the art to add a salt to increase solubility of an insoluble active.

Response to Amendment/Arguments

The Rule 132 Declaration under 37 CFR 1.132 filed 8/19/04 is insufficient to overcome the rejection of the claims based upon Bazzano (5183817) in view of WO 97/12602 as set forth in the last Office action because:

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The applicant states that the addition of lactic acid to Bazzano's composition is not possible since lactic acid does not increase the solubility of retinoic acid and that the results demonstrate that the solubility of retinoic acid is negligible.

Firstly, it is pointed out that the rejection is not based on the fact that Weiner's lactic acid will increase the solubility of the retinoic acid, the examiner's motivation to combine the references is that lactic acid increase the solubility of minoxidil. Not only does Weiner state an organic acid increases minoxidil's solubility, this is the same argument asserted by the applicant. Therefore, it is clear that the prior art recognizes this function of the instant acids.

Additionally, it is pointed out that Bazzano teaches that the composition may contain minoxidil or its derivatives or analogs. See column 1, lines 22-25. Bazzano states that the active derivatives and analogs that are described in US patents 5910928, 3637697, 3461461, 4139619, and 4596812 are incorporated into the reference. US patent 3,461,461 for instance teaches the acid salt derivatives including lactic acid and other instantly claimed acids. See column 8, line 68. Therefore, it is clear that the lactic acid may be added.

Secondly, the examiner points out that the instant claim language does not exclude the use of other agents such as retinoic acid, in the composition.

Claims 1-4, 5-6, 8-9, 12-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/25500 to Navarro et al (abstract only) in view of WO 97/12602 to Weiner et al.

Navarro teaches a hair care composition containing 0.1-7% minoxidil, 0.1-3% cyclodextrin, 0.5-10% minoxidil of a solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples.

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Navarro does not teach the use of lactic or acetic acid.

Weiner teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Weiner teaches that a number of different modifications may be made to the minoxidil. One such modification is provided by] reacting minoxidil with an organic acid such as lactic acid. The minoxidil may also be converted to a salt by reacting it with a cyclodextrin. See page 3. Weiner states that the use of a minoxidil acid salt addition provides substantial penetration and cyclodextrin salt addition is the “next best”. See page 7.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Navarro et al and Weiner et al and substitute Navarro’s cyclodextrin with the instant acid to convert minoxidil into a salt. One would be motivated to do so since Weiner teaches that by converting the minoxidil to a hydrophilic compound, it penetrates the skin. More specifically, Weiner teaches the conversion of minoxidil into a salt form by reacting it with an organic acid such as lactic acid or with cyclodextrin and notes that although both provide penetration of minoxidil, the acid salt addition has a better effect than the cyclodextrin salt addition. Therefore, one would have been motivated to use an acid salt addition to convert minoxidil into a hydrophilic compound rather than Navarro’s cyclodextrin since Weiner teaches the acid salt addition has better penetration into the skin.

Response to Amendment/Arguments

The Rule 132 Declaration under 37 CFR 1.132 is insufficient to overcome the rejection of claims based upon Navarro et al in view of Weiner et al as set forth in the last Office action because:

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The examiner points out that the rejection has been modified. It is the examiner's position that since Weiner teaches not only the acid salt addition but also a cyclodextrin addition and compares it, one would have been motivated to substitute Navarro's cyclodextrin with the instant salt since Weiner compares the two and states that the salt addition has better efficacy. Therefore, the Declaration no longer applies to the instant rejection since the question whether cyclodextrin is acid labile is moot.

For arguendo sake, the examiner points out that the Rule 132 provides only a opinion without evidence. Thus, an opinion declaration without factual evidence is not given little weight. It is noted that applicant submitted articles to support his opinion. However, the articles merely state that cyclodextrin is degraded in an acid solution. The examiner points out that the acid is added in an amount to make minoxidil into a hydrophilic compound and not in an amount that is strong enough to degrade the cyclodextrin.

Claims 10-11, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of WO 97/12602, in further view of Uchikawa et al (5156836).

Bazzano teaches a minoxidil composition to increase growth rate and stimulate new hair growth by administering a lotion containing 0.01-0.1% retinoic acid, 0.5-5% minoxidil, ethanol, 5-50% propylene glycol, 0.1% BHT, and distilled water (up to 10%). WO teaches reacting minoxidil with an organic acid such as lactic acid to increase its penetration into the skin. See page 4.

The references do not teach the use of benzyl alcohol.

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Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34). Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to combine the teachings of Bazzano, WO, and Uchikawa and utilize benzyl alcohol in the solvent system. One would have been motivated to do so since Uchikawa et al teach the use of either ethanol or benzyl alcohol as functional equivalents, i.e. solvents, in the hair tonic. Therefore, it is prima facie obvious to substitute one equivalent solvent for another, i.e. Bazzano's ethanol with instant benzyl alcohol, since the prior art establishes that both are functionally equivalent and are utilized for the same purpose.

Response to Arguments

Applicant argues the Rule 132 Declaration overcomes the instant rejection.

Applicant's arguments have been fully considered but they are not persuasive. The merits of the Rule 132 declaration as been addressed above.

Claims 10-11, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/25500 to Navarro et al (abstract only) in view of WO 97/12602 to Weiner et al in further view of Uchikawa et al (5,156,836).

As set forth above, WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-3% cyclodextrin, 0.5-10% minoxidil of a solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples. Weiner teaches reacting

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minoxidil with an organic acid such as lactic acid to increase its penetration into the skin. See page 4.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol and benzyl alcohol. Further, the reference teaches a formulation where the alcohol-water mixture is in the instant ratio. (col. 3 and 4, line 45 through line 34). Uchikawa et al teaches the application of the hair composition for the treatment of hair loss.

It would have been obvious at the time the invention was made to combine the teachings of Navarro et al, Weiner et al, and Uchikawa and utilize benzyl alcohol in the solvent system. One would have been motivated to do so since Uchikawa et al teach the use of either ethanol or benzyl alcohol as functional equivalents, i.e. solvents, in the hair tonic. Therefore, it is prima facie obvious to substitute one solvent for another, i.e. WO's ethanol with instant benzyl alcohol, since the prior art establishes that both are functionally equivalent and are utilized for the same purpose.

Response to Arguments

Applicant argues the Rule 132 Declaration overcomes the instant rejection.

Applicant's arguments have been fully considered but they are not persuasive. The merits of the Rule 132 declaration have been addressed above.

Claims 1-3, 5-6, 8-9, 12-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Schiena (4866067) in view of WO 97/12602.

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Di Schiena discloses minoxidil (0.1-10%, ex: 5%) combined with oxyniacic acid for topical treatment of alopecia. The reference discloses that minoxidil is insoluble in water and the salt form of minoxidil is soluble in a water-based composition. Therefore, an acid makes it remarkably soluble in water without loading the composition with glycols. Di Schiena discloses a foam composition containing the instant active, water, a lower alcohol, and propylene glycol (9%) in a foam composition (note examples). The foam composition also contains cetyl alcohol and a surfactant. Di Schiena teaches methanol, ethanol, or isopropanol as suitable solvents (col. 2, lines 17-20 and examples. Further, the reference exemplifies a lotion containing the active without the use of a glycol, instant amount of water, ethanol, and active (example b). The examples teach a variety of water to lower alcohol ratios.

Di Schiena does not teach the use of lactic or acetic acid.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Di Schiena and WO and utilize the instant acids. One would have been motivated to do so since WO teaches that organic acids modify minoxidil to yield a hydrophilic active and therefore is more soluble in water and improves penetration into the hair follicle. Therefore, since Di Schiena also teaches the use of an organic acid to improve solubility it is within the skill of an artisan to substitute another acid with the expectation of similar results.

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In regards to the claimed ratio of 17, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to manipulate the parameters set forth in Di Schiena. One would have been motivated to do so as part of routine experimentation to yield the best possible results. Differences in concentration do not extend patentability to subject matter encompassed in the prior art unless there is evidence indicating criticality.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
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